

APPENDIX A

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference IMG/44660PCT	FOR FURTHER ACTION		see Form PCT/ISA/220 as well as, where applicable, item 5 below.
International application No. PCT/GB2004/003940	International filing date (day/month/year) 15/09/2004	(Earliest) Priority Date (day/month/year) 15/09/2003	
Applicant VECTURA LIMITED			

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 5 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ The international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

b. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☐ **Certain claims were found unsearchable** (See Box II).

3. ☒ **Unity of invention is lacking** (see Box III).

4. With regard to the **title**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the **drawings**,

a. the figure of the **drawings** to be published with the abstract is Figure No. 2

☐ as suggested by the applicant.

☒ as selected by this Authority, because the applicant failed to suggest a figure.

☐ as selected by this Authority, because this figure better characterizes the invention.

b. ☐ none of the figures is to be published with the abstract.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/GB2004/003940

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1-22

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-22

A dry powder inhaler having a primary and secondary piercing elements

2. claims: 23-31

A medicament pack having a drug storage chamber and aerosolizing nozzle

INTERNATIONAL SEARCH REPORT

International Application No

PCT/GB2004/003940

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M15/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2001/029948 A1 (INGLE FRANK W ET AL) 18 October 2001 (2001-10-18)	1,2,4,5, 7-10,15, 16,19-21
Y	paragraphs [0041] - [0045]; figures -----	3,6,22
X	US 2002/017297 A1 (BURR JOHN D ET AL) 14 February 2002 (2002-02-14)	1,2,4,5, 7-10,15, 19-21
Y	paragraphs [0054] - [0063]; figures 3-8 -----	3,6,22
A	WO 02/089879 A (EASON STEPHEN WILLIAM ; HARMER QUENTIN JOHN (GB); CLARKE ROGER WILLIAM) 14 November 2002 (2002-11-14) page 31, line 24 - page 34, line 27; figures 28-32b ----- DE 30 16 127 A (SIGMA TAU IND FARMACEUTI) 20 November 1980 (1980-11-20) the whole document -----	1

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

29 November 2004

Date of mailing of the international search report

02.02.2005

Name and mailing address of the ISA

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Authorized officer

Vänttinen, H

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/GB2004/003940

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2001029948 A1	18-10-2001	AU 2580101 A	25-06-2001
		AU 2727901 A	25-06-2001
		CA 2393615 A1	21-06-2001
		EP 1237608 A2	11-09-2002
		JP 2003516780 T	20-05-2003
		MX PA02006011 A	28-01-2003
		TW 470656 B	01-01-2002
		TW 480183 B	21-03-2002
		WO 0143529 A2	21-06-2001
		WO 0143530 A2	21-06-2001
		US 2001029947 A1	18-10-2001
US 2002017297 A1	14-02-2002	US 6257233 B1	10-07-2001
		US 2003209243 A1	13-11-2003
		AU 775629 B2	05-08-2004
		AU 4090599 A	20-12-1999
		BG 105113 A	28-06-2002
		BR 9910931 A	16-10-2001
		CA 2332853 A1	09-12-1999
		CN 1312729 T	12-09-2001
		EA 2869 B1	31-10-2002
		EE 200000721 A	15-04-2002
		EP 1082155 A2	14-03-2001
		HR 20010008 A1	31-12-2001
		HU 0103610 A2	28-02-2002
		ID 29131 A	02-08-2001
		JP 2003527136 T	16-09-2003
		MA 24907 A1	01-04-2000
		NO 20006167 A	05-02-2001
		NZ 508536 A	28-03-2003
		PL 345179 A1	03-12-2001
		SK 18162000 A3	02-07-2002
		TR 200003611 T2	21-06-2001
		TW 509069 Y	01-11-2002
		WO 9962495 A2	09-12-1999
		EG 22154 A	30-09-2002
		ZA 200006920 A	25-02-2002
WO 02089879 A	14-11-2002	GB 2375308 A	13-11-2002
		CA 2444729 A1	14-11-2002
		WO 02089879 A1	14-11-2002
		WO 02089880 A2	14-11-2002
		WO 02089881 A1	14-11-2002
		EP 1392382 A1	03-03-2004
		EP 1392383 A2	03-03-2004
		GB 2375309 A	13-11-2002
		GB 2375310 A	13-11-2002
		US 2004159321 A1	19-08-2004
		US 2004211419 A1	28-10-2004
DE 3016127 A	20-11-1980	IT 1116047 B	10-02-1986
		DE 3016127 A1	20-11-1980
		ES 8102816 A1	16-05-1981
		FR 2454813 A1	21-11-1980
		GB 2048689 A	17-12-1980
		JP 56015759 A	16-02-1981
		US 4338931 A	13-07-1982

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

To:

see form PCT/ISA/220

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY
(PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/GB2004/003940

International filing date (day/month/year)
15.09.2004

Priority date (day/month/year)
15.09.2003

International Patent Classification (IPC) or both national classification and IPC
A61M15/00

Applicant
VECTURA LIMITED

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/GB2004/003940

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ in written format
 - ☐ in computer readable form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in computer readable form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/GB2004/003940

Box No. II Priority

1. ☒ The following document has not been furnished:

☒ copy of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(a)).

☐ translation of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(b)).

Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.

3. ☐ It has not been possible to consider the validity of the priority claim because a copy of the priority document was not available to the ISA at the time that the search was conducted (Rule 17.1). This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

4. Additional observations, if necessary:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/GB2004/003940

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 23-31

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the whole application or for said claims Nos. 23-31

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

☐ has not been furnished

☐ does not comply with the standard

the computer readable form

☐ has not been furnished

☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☐ See separate sheet for further details

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/GB2004/003940

Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees, the applicant has:
- ☐ paid additional fees.
 - ☐ paid additional fees under protest.
 - ☒ not paid additional fees.
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is
- ☐ complied with
 - ☒ not complied with for the following reasons:
see separate sheet
4. Consequently, this report has been established in respect of the following parts of the international application:
- ☐ all parts.
 - ☒ the parts relating to claims Nos. 1-22

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	3,6,11-14,17,18,22
	No: Claims	1,2,4,5,7-10,15,16,19-21
Inventive step (IS)	Yes: Claims	11-14,17,18
	No: Claims	1-10,15,16,19-22
Industrial applicability (IA)	Yes: Claims	1-22
	No: Claims	

2. Citations and explanations

see separate sheet

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/GB2004/003940

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

1 Concerning Re Item IV.

It is clear already a priori that claims 1 and 23 relate to completely different products and that they cannot have any common or corresponding special technical features as required by Rule 13.2 PCT. Consequently, they are not so linked as to form a single general inventive concept (Rule 13.1 PCT). The separate inventions/groups of inventions are:

Claims 1-22: A dry powder inhaler having a primary and secondary piercing elements

Claims 23-31: A medicament pack having a drug storage chamber and aerosolizing nozzle

2 Concerning Item V.

2.1 US-A-2001/029948 (D1) discloses a dry powder inhaler comprising a drug entrainment device having a drug outlet tube (116) terminating with a primary piercing element (118), a secondary piercing member (114) to pierce a plurality of peripheral openings, and an airflow path (126 → 124 → 120 → 108 → 112 → 104 → 116) as defined in claim 1. Thus, the subject-matter of claim 1 does not meet the requirement of Article 33(2) PCT. In addition, also US-A-2002/017297 (D2, see Figs. 3-8) is considered to disclose a device which falls under the wording of claim 1.

2.2 Furthermore, the technical features of dependent claims 2, 4, 5, 7-10, 15, 16 and 19-21 appear to be known from D1. Thus, said claims do not meet the requirement of Article 33(2) PCT.

2.3 The technical features of claims 3, 6 and 22 appear to be obvious for the skilled person from the teaching of WO-A-02/089879 (D3). Thus, the subject-matters of said claims do not appear to meet the requirement of Article 33(3) PCT.

2.4 The technical features of the remaining dependent claims 11-14, 17 and 18 do not appear to be derivable from any of the cited documents in an obvious manner. Consequently, said claims appear to meet the requirements of Article 33(2) and (3) PCT.

2.5 The industrial applicability (Article 33(4) PCT) of a device according to the claims 1-

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

International application No.

PCT/GB2004/003940

22 is self-evident.

3 Concerning Item VII

The closest prior art (D1) has not been identified as required by Rule 5(a)(ii) PCT. Furthermore, the independent claims are not in the two-part form as required by Rule 6.3(b) PCT. In addition, the claims do not include reference signs in parentheses as required by Rule 6.2(b) PCT.